

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

WAVE NEUROSCIENCE, INC.,	
Plaintiff,	
vs.	Civil Action No. 5:23-cv-00626-XR
BRAIN FREQUENCY LLC,	
Defendant.	Demand for Jury Trial

DECLARATION OF SHANNON LEA MALISH, LCSW-S

1. My name is Shannon Lea Malish, LCSW-S. I am over the age of 18 years old, of sound mind, and competent to make this declaration. The facts stated herein are true and correct and within my personal knowledge.

2. I am a Licensed Clinical Social Worker & Supervisor (“LCSW-S”) licensed in the State of Texas from Texas State Board of Social Workers Examiners (License # 57103). I have a Master’s degree from the University of Texas - San Antonio in Social Work with an emphasis in addiction counseling. I am one of the founding members of the Society of Evidenced-Based Addiction Treatment (“SEAT”) the purpose of which is to establish the standards of care for addiction treatment. I am a member of American Society of Addiction Medicine (“ASAM”). I have specialized training in the delivery and application of Eye Movement Desensitization and Reprocessing (“EMDR”) therapy. I have specialized training and have been certified by the neuroCademy (Germany) in the delivery and application of repetitive Transcranial Magnetic Stimulation (“rTMS”), specifically for depression, OCD, and new developments and modalities in

the field. I am a Texas Certification Board provider of Continuing Education for certification and recertification of alcoholism and drug abuse counselors in the State of Texas (License #1918-14).

3. I have over 13 years of experience facilitating the diagnosis and treatment of thousands of patients suffering from such mental disorders, including those with addiction, depression and PTSD.

4. I am also the Founder and Chief Executive Officer of Defendant Brain Frequency LLC (“Brain Frequency”). Brain Frequency provides software technology to assist with the treatment of individuals suffering from mental disorders and conditions including, trauma, post-traumatic stress disorder, addiction, depression and anxiety, among other conditions.

5. During my experience as a LCSW-S, I have gained substantial experience and knowledge treating clinical patients using Transcranial Magnetic Stimulation (“TMS”), which is a widely known therapy of providing magnetic stimulation to treat affected areas of the brain. As a result of this extensive experience, I realized that TMS—in combination with a patient’s EEG data—has historically provided positive results for mental therapy and as a result of using Neuro-Bio Feedback and Eye Movement Desensitization and Reprocessing (EMDR), and I set out to improve the methods to facilitate even more effective treatments using TMS. After years of clinical research, I discovered certain patterns in areas of the brain (as measured by EEG data) correlating to certain mental disorders. These efforts eventually led to development of Brain Frequency’s proprietary software (hereinafter the “Brain Frequency Software”) which analytically diagnoses a patient’s EEG measurements to more precisely indicate the areas of the brain of the patient that are negatively impacted. The Brain Frequency Software provides unique analytics of a patient’s data in order to more efficiently diagnose and target how TMS should be used for much more effective results.

6. Brain Frequency licenses the Brain Frequency Software to a total of five individual medical practitioners or medical organizations that exclusively treat patients with medical disorders. The primary purpose of the software is to assist doctors and clinicians with more effective diagnosis and treatments.

7. Each of Brain Frequency's licensees are medical practitioners or those acting under the direction and supervision of medical practitioners who are licensed by the State of Texas or other states to diagnose and treat medical patients. **Exhibit 5**, attached hereto, is a true and correct copy of an exemplar of the contractual agreements entered into between Brain Frequency and its licensees.

8. Each of Brain Frequency's medical practitioner licensees provide medical diagnosis or treatment (including options to rule out and isolate possible diagnoses, treatments and protocols) to medical patients using the Brain Frequency Software pursuant to the contractual agreements entered into between Brain Frequency and the medical practitioners.

9. Pursuant to the contractual agreements between Brain Frequency and its licensees, the Brain Frequency Software is intended to be used exclusively for the purpose of engaging in medical activities, namely, the diagnosis and treatment of medical patients (including options to rule out and isolate possible diagnoses, treatments and protocols).

10. Brain Frequency only provides software to assist in the facilitation of treatments, mainly in conjunction with EEG and TMS devices. Brain Frequency does not provide or sell TMS or EEG devices. Brain Frequency does not design, manufacture, develop, make, or sell machines, or parts or components of machines, such as TMS and EEG devices. The Brain Frequency Software itself is not a machine and is not used to manufacture patented machines, nor is it a

composition of matter. It also does not involve the use of biological materials or clinical laboratory services.

11. The Brain Frequency Software is not regulated by the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Clinical Laboratories Improvement Act, or the Food and Drug Administration.

12. Brain Frequency does not make, sell, offer to sell, or market any products regulated by the Food and Drug Administration or any other regulatory agency.

13. I have reviewed the allegations in the Plaintiff's Second Amended Complaint regarding my appearance on the Longevity Podcast in November 2022. My appearance on that Podcast was for the purpose of providing educational information to medical practitioners and others about the benefits of using the Brain Frequency Software to diagnose and treat patients, (including options to rule out and isolate possible diagnoses, treatments and protocols), not for the purpose of advertising, marketing, or promoting the Brain Frequency Software for commercial gain.

14. I have also reviewed the information on Brain Frequency's website at <https://brainfrequency.ai/treatment-process>. In my professional opinion, this information relates to the dissemination of educational information to medical practitioners and others about the benefits of using the Brain Frequency Software to diagnose and treat patients and was not included on Brain Frequency's website for the purpose of advertising, marketing, or promoting the Brain Frequency Software for commercial gain.

15. I have reviewed the Plaintiff's Second Amended Complaint and Plaintiff's Infringement Contentions, and I understand that Plaintiff alleges that Brain Frequency infringes

the following patents: U.S. Patent Nos 10,029,111 (the “’111 Patent”); 8,465,408 (the “’408 Patent”); and 8,870,737 (the “’737 Patent) (the “Asserted Patents”).

16. I have also reviewed each specific claim that Plaintiff alleges is infringed by Brain Frequency. Based on my plain review of the patent claims and based on my professional experience and judgment, each of the asserted claims of the Asserted Patents alleged to be infringed by Brain Frequency and Brain Frequency’s Software relate to a medical activity or procedure that is required to be performed by a medical practitioner (or at the supervision or direction of a medical practitioner) on a medical patient.


17. With respect to U.S. Patent No. 10,029,111, I understand the Plaintiff alleges Brain Frequency infringes Claims 1 and 3-7 of the ’111 Patent. I have reviewed each of those claims. Based on my plain review, as well as my professional experience in the medical profession, each of the claims relate to the performance of a medical activity or procedure on a body by a medical practitioner. For example, claim 1 of the ’111 Patent is directed to “[a] method of improving a physiological condition or a neuropsychiatric condition...”

18. With respect to U.S. Patent No. 8,465,408, I understand the Plaintiff alleges Brain Frequency infringes at least Claims 1-4 and 9-10 of the ’408 Patent. I have reviewed each of those claims. Based on my plain review, as well as my professional experience in the medical profession, each of the claims relate to the performance of a medical activity or procedure on a body by a medical practitioner. For example, claim 1 of the ’408 Patent is directed to “[a] method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD)...”

19. With respect to U.S. Patent No. 8,870,737, I understand the Plaintiff alleges Brain Frequency infringes at least Claims 1-4, 8-9, and 11 of the ’737 Patent. I have reviewed each of those claims. Based on my plain review, as well as my professional experience in the medical

profession, each of the claims relate to the performance of a medical activity or procedure on a body by a medical practitioner. For example, title of the '737 Patent is "...methods for Neuro-EEG Synchronization Therapy." Further the summary of the invention in the patent specification "methods and systems for novel, inexpensive, easy to use therapy for a number of mental disorders."

I declare under penalty of perjury that the foregoing is true and correct.


Declarant

Executed in Comal County, State of Texas, on the 2 day of May 2024.